IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Roddi James SIMPSON et al.	
Serial No. 10/657,171	Art Unit: 3763
Filed: September 9, 2003	Examiner: Han, Mark K.
For: FIXED NEEDLE SYRINGE WITH PROTECTIVE HOUSING	Atty Docket: 0100/0162

DECLARATION FILED PURSUANT TO 37 C.F.R. 1.132

Frederick P. Zecha, hereby declares:

(1) That he is Director of Business Development for Needle Protection and Arterial Blood Sampling for Smiths Medical ASD, Inc., and has been employed by Smiths Medical ASD, Inc., and its predecessor corporate entity Portex, Inc. , since ; June, 1984

(2) That he has been continuously employed in the needle protection field for the past 17 years and has substantial knowledge about the various types of needle devices in the market;

(3) That he is knowledgeable of the development of the syringe product covered by the claims of the instant application, now sold in the market under the trade name Hypodermic Needle-Pro Fixed Needle Insulin Syringe (Fixed Needle Syringe), substantially from the time that the product was conceived and developed by the inventors of the instant application, to the launch of the product up to the present;

(4) That Appendix A attached to the instant application contains an accurate representation of the invention disclosed in the instant application. The Fixed Needle Syringe disclosed on page 2 of the Appendix A brochure is covered by at least the independent claims of the instant application;

(5) That prior to the introduction of the Fixed Needle Syringe covered by the instant application, there is available in the market a number of alternative devices sold by a number of different companies. These devices are listed under the heading "Injection Devices" on pages 2-3 of the article entitled "List Of Safety-Engineered Sharp Devices", which is attached as Appendix B;

(6) That the product shown in Appendix C under "Safety Needles", a product being sold by the assignee of the instant invention, is similar to and is representative of the needle assembly disclosed in Fig. 11 of the prior art reference Burns (USP 5,643,219) which the examiner has relied upon for rejecting the claims of the instant application;

(7) That since its introduction in September 2003, the Fixed Needle Syringe disclosed in Appendix A and covered by the claims of the instant application has achieved commercial success both in the United States and abroad; that this success of the Fixed Needle Syringe is not the result of any heavy promotion or advertising, or shifting in advertising from other products carried by the assignee of the instant application to the Fixed Needle Syringe;

(8) That since its introduction in 2003, the Fixed Needle Syringe has captured 5% of the insulin syringe market; that sales for the Fixed Needle Syringe for the introduction year 2003 was $ 2,464,576 in the United States and $ 20,500 overseas; and for fiscal year 2004 sales was $ 4,974,585 and $ 31,000

(9) That the commercial success of the Fixed Needle Syringe is believed to be due to the fact that it is a unitary syringe with its fixed sterile needle capped prior to use, and a needle protection housing rotatably mounted about the distal end of the syringe, so that the user only needs to remove the cap to use the syringe; and that the user no longer needs to carry separately both a needle assembly (such as the exemplar device

shown in Appendix C) and a conventional syringe, and then having to attach the needle assembly to the syringe prior to use;

(10) That the Fixed Needle Syringe is, according to users, much more convenient to use; and

(11) That the Fixed Needle Syringe also solves a long felt need by eliminating the need for the user to carry both a needle assembly with a needle protection housing and a conventional needle syringe.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued there from.

Frederick P. Zecha Date 12/07/05